

Intelligence Applied to Biomarkers in Clinical Drug Development.



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MDS Pharma Services Bioanalytical applies its collective knowledge and experience *intelligently* to help streamline your drug discovery and development process. Our expertise in the area of biomarkers is simply another way we are working to help you speed your compound to market.

Providing more complete pharmacodynamic information on safety and efficacy earlier in the drug development process is a key factor in increasing efficiency. Biomarkers can play an essential role. MDS Pharma Services is at the forefront of this emerging paradigm—our staff has extensive experience in using biomarkers to establish proof of concept, in PK/PD modeling, to stratify the patient responder, and to select the right drug candidate.

Our capabilities in biochemical markers help you develop mechanistic-based biomarker relationships to discover manifestation. They also help you understand subtle differences in a drug's intervention activity profile. In these ways, biomarkers help you promote promising compounds and filter undesirable ones. With reliable biomarker data, you can make early decisions with greater confidence.

Unsurpassed scientific expertise. No CRO has more experience in biomarkers than MDS Pharma Services. We have an outstanding staff of published scientists who are highly knowledgeable in the analysis of both small and large biomarker molecules. MDS Pharma Services provides extensive experience in genomics/proteomics and diagnostics, adding considerable breadth and strength in identifying novel markers and monitoring drug effects on patients. And, our close ties with biomarker experts in the academic communities and at the NIH allow us to tap important outside resources for additional support.



A high level of collaboration. We have a responsive team of scientists who work closely with your drug development group. Clinical, clinical pharmacologists, biologists, biochemists, and bioanalysts collaborate in an integrated approach for biomarker selection, development, and validation of biomarkers.

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Biomarker menus. MDS Pharma Services uses our extensive expertise and knowledge to proactively establish menus of biomarkers according to disease and mechanism. Current menus include:

- * Immune modulation (asthma, rheumatoid arthritis)
- * Diabetes
- * Coagulation
- * Bone markers

Additional biomarkers are being validated regularly and our list is constantly updated. Please visit our Web site at www.mdsps.com for the complete list.



Ligand-binding assays. The majority of biomarkers are proteins, which are analyzed by ligand-binding assays. At our facilities in Zurich, Switzerland; Saint-Laurent, Quebec; and Lincoln, Nebraska, MDS Pharma Services has outstanding capabilities for the development of this type of assay. Our large capacity offers you a higher level of parallel work, as we can run multiple assays simultaneously for increased throughput. In addition, we have enzyme activity and cell-based assay capabilities for functional assays of the biomarkers.

Method validation. Currently, regulatory guidance on biomarker validation is limited. Beginning as early as 1996, our scientists have helped shape the industry standards for biomarker bioanalysis.

As a leader in this field, MDS Pharma Services understands the various issues at hand and will work with you to develop and validate methods, taking into account all factors in order to meet the intended purpose of the study. We can state with confidence that our validation methods are GLP-similar when appropriate.

We survey levels of biomarkers in healthy subjects and patients to define the activity or concentration ranges, select the proper study matrix, test method, and check dilution linearity. We provide data with the highest level of precision and accuracy possible to help you make the optimal decisions.

For more information, visit our Web site at www.mdsps.com.

The integrated paradigm of biomarkers to support clinical drug development is still new, but MDS Pharma Services is already highly experienced. No other CRO can offer you this level of expertise. Contact us today to find out how we can customize a program to best meet your needs.



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